# **AMENDMENTS**

#### In the claims:

Please amend Claim 11 to read as follows.

1.(previously presented) An isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1.

- 2. (original) An isolated nucleic acid molecule comprising a nucleotide sequence that:
  - (a) encodes the amino acid sequence shown in SEQ ID NO: 2; and
  - (b) hybridizes under stringent conditions to the nucleotide sequence of SEQ ID NO: 1 or the complement thereof.
- 3.(original) An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 2.
- 4.(original) An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:4.
  - 5. 10. (cancelled)
- 11.(currently amended) An expression vector comprising [a] the nucleic acid sequence of Claim 4.
  - 12.(previously presented) A cell comprising the expression vector of Claim 11.

#### **RESPONSE**

## I. Status of the Claims

Claim 11 has been amended as suggested by the Examiner. Claims 1-4, 11 and 12 are pending .

# II. Support for the Amended Claims

Amended Claim 11 finds support in original Claim 11 which found support in original Claim 4, throughout the specification as originally filed with particular support being found at least on page 13, lines 25-32.

As the amendments to Claim 11 are fully supported by the specification and claims as originally filed, they do not constitute new matter. Entry therefore is respectfully requested.

# III. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

Clam 11 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Although Applicants in no way agree, in order to further progress this application towards allowance, Claim 11 has been amended exactly as the Examiner requested and thus this rejection has been avoided and Applicants' therefore request its withdrawal.

# IV. Rejection of Claims Under 35 U.S.C. § 101

The rejection of claims 1-4, 11-12 under 35 U.S.C. § 101 is maintained because the claimed invention allegedly is not supported by either a specific and substantial asserted utility or a well-established utility. This rejection is respectfully traversed, based on the following arguments as well as those presented in earlier responses.

The rejection of claims 1-4 is maintained in this Final Action which again asserts that Applicants have failed to identify the function of the protein encoded by the sequences of the present invention and that therefore there can be no specific, substantial or credible utility.

The Final Action dismisses Applicants' continued assertions that the protein of the present invention is a human semaphorin protein and that semaphorin protein function is both well known and implied to those of skill in the art. The Action at page 3, line 5, cites Bork (Genome Research 10:398-400, 2000) as supporting the proposition that prediction of protein function from homology information is somewhat unpredictable. However, a careful reading of Bork's publications and the other "relevant literature" does not in fact support the concept that function cannot be based on sequence and structural similarity, in contrast many of the examples actually support the use of such methodologies while identifying several areas in which caution should be exercised. These inaccuracies and potential pitfalls can be overcome by a more careful analysis by those of skill in the art. Automatic methods of sequence homology identification was only the staring point for consideration the sequences of the present invention underwent careful analysis by a series of individuals of skill in the art, many highly qualified (B.S. and Ph.D. level scientists).

These articles are merely examples of a small number of spurious publications that call into doubt the usefulness of bioinformatic predictions and that the PTO has repeatedly attempted to use as a basis to deny the utility of nucleic acid sequences. However, without going into the merits (or lack thereof) of all of the cited articles, Appellants point out that the lack of 100% unanimous agreement on the usefulness of bioinformatic prediction programs is completely irrelevant to the question of whether the claimed nucleic acid sequence has a substantial and specific utility. Appellants respectfully point out that the legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be **believable**. Appellants submit that the overwhelming majority of those of skill in the relevant art would **believe** bioinformatic prediction to be a powerful and useful tool, as evidenced by hundreds if not thousands of journal articles.

Rather, the question of utility is a straightforward one. As set forth by the Federal Circuit, "(t)he threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip Inc. v. Orange Bang Inc.*, 51 USPQ2d 1700 (Fed. Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)). Additionally, the Federal Circuit has stated that "(t)o violate § 101 the claimed device must be <u>totally incapable</u> of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992), emphasis added. *Cross v. Iizuka* (224 USPQ 739 (Fed. Cir. 1985); "*Cross*") states "any utility of the claimed compounds is sufficient to satisfy 35 U.S.C. § 101". *Cross* at 748, emphasis added.

Indeed, the Federal Circuit recently emphatically confirmed that "anything under the sun that is made by man" is patentable (*State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 47 USPQ2d 1596, 1600 (Fed. Cir. 1998), citing the U.S. Supreme Court's decision in *Diamond vs. Chakrabarty*, 206 USPQ 193 (S.Ct. 1980)).

The legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. According to the Examination Guidelines for the Utility Requirement, if the applicant has asserted that the claimed invention is useful for any particular purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, the Examiner should not impose a rejection based on lack of utility (66 Federal Register 1098, January 5, 2001).

As evidence of the credibility of Applicants assertion that the present invention is a variant of human semaphorin sem 2, In Applicants' response to the First Office Action (Paper No. 13) Applicants' submitted an amino acid sequence comparison between SEQ ID NO: 3 and BAA98132 (as Exhibit E), which was annotated by third party scientists, wholly unaffiliated with Applicants, as encoding semaphorin sem2 [Homo sapiens] (BAA98132: as Exhibit F). In this submission was included evidence that SEQ ID NO: 1 (see previously submitted Exhibit G comparing SEQ ID NOS: 3 and 1) identifies a longer isoform of the present invention, which is clearly encoded by the same genetic locus. Clearly those of skill in the art would recognize the sequences of the present invention as encoding a human semaphorin. As evidenced by the review article entitled "Molecular Mechanisms of Axonal Guidance" from the prestigious journal Science (298:1959-1964, 2002 and erratum; previously submitted as Exhibit H in Paper No. 13), semaphorins are well known to those of skill in the art as soluble and membrane-bound proteins that act as chemorepulsive factors in neuronal development, thereby playing a crucial role in axon guidance. Semaphorins, such as the one described in the present invention, provide guidance for neuronal growth. In the second paragraph of Section 5.1 or the specification as filed, it is stated that "Because of their role in neural development, semaphorins have been subject to considerable scientific scrutiny. For example, U.S. Patents Nos. 5,981,222 and 5,935,865, both of which are herein incorporated by reference, describe other semaphorins as well as applications, utilities". Therefore, clearly, there can be no question that Applicants' asserted identity and utility for the described sequences a semaphorin is "credible." In addition, those of skill in the art in the biomedical and pharmaceutical industry would readily recognize the utility for semaphorins and

their application to medical conditions requiring nerve regeneration. For example, the regeneration and repair of nerve tissue following the surgical attachment of severed limbs or the resection of diseased tissue, as well as nerve repair following a stroke.

Further support of Applicants' position that the function of the protein encoded by the sequences of the present invention is that of semaphorin sem 2 is further provided by the nucleotide sequence encoding the previously presented protein (BAA98132) shares 99.957 % percent homology over the entire nucleic acid sequence of SEQ ID NO:3 (nucleic acid alignment presented as New Exhibit AA; GenBank accession number AB029496).

Applicants have thus supplied evidence supporting their assertion that those of skill in the art would recognize that the sequences of the present invention encode variants of human semaphorin. Applicant's assertion also supports a "well-established" utility in that persons of ordinary skill in the art would immediately appreciate. In contrast, the Examiner has provided no evidence of record indicating that those of skill in the art would not recognize the sequences of the present invention encode semaphorin. As such, the scientific evidence clearly establishes that Applicants have described an invention whose utility is in full compliance with the provisions of 35 U.S.C. § 101, and therefore Applicants respectfully request withdrawal of the rejection.

The Final Action states that there is no disclosure in the specification suggesting that the sequences of the present invention as encoding the biological activity of human semaphorins (page 3 lines 9-10). However, the application clearly identifies similarities between the sequences of the present invention (SEQ ID NOS: 1-5) and semaphorin proteins (at least on page 2, lines 14-15; page 4, lines 10-11 and page 17, line 10) and their tissue expression distribution (page 4, lines 10-15) and describes the activity of semaphorins (page 4, lines 10-15) and well-established utility "Because of their role in neural development, semaphorins have been subject to considerable scientific scrutiny. For example, U.S. Patents Nos. 5,981,222 and 5,935,865, both of which are herein incorporated by reference, describe other semaphorins as well as applications, utilities, and uses ..." (page 17, lines 14-18). Clearly Applicants were aware at the time of filing of the semaphorin like nature of the protein encoded by sequences of the present invention.

Furthermore the Examiner's position that mere homology of SEQ ID No:1 to a known DNA molecule with a known function does not endow SEQ ID NO:1 with the function is contrary to Example 10 of the PTO's Revised Interim Utility Guidelines Training Materials (pages 53-55), which

establishes that a rejection under 35 U.S.C. § 101 as allegedly lacking a patentable utility and under 35 U.S.C. § 112, first paragraph as allegedly unusable by the skilled artisan due to the alleged lack of patentable utility, is not proper when there is no reason to doubt the asserted utility of a full length sequence (such as the presently claimed sequence) that has a similarity score of 95% to a protein having a known function. In the Analysis portion of Example 10 it states that "Based on applicant's disclosure and the results of the PTO search, there is no reason to doubt the assertion that SEQ ID NO:2 encodes a DNA ligase. Further DNA ligases have a well-established use in the molecular biology art based on this class of proteins ability to ligate DNA. ......Note that if there is a well-established utility already associated with the claimed invention, the utility need not be asserted in the specification as filed...... Thus the conclusion reached from this analysis is that a 35 U.S.C. § 101 and a 35 U.S.C. § 112 first paragraph, utility rejection should not be made."

The present case is similar to that presented in Example 10 of the Revised Interim Utility Guidelines Training Materials (pages 53-55). In the present case it is clear that the sequences of the present invention encode a semaphorin. Semaphorins have a well-established function. Thus a 35 U.S.C. § 101 and a 35 U.S.C. § 112 first paragraph, utility rejection should not have been made and should therefore, be withdrawn.

As set forth in In re Langer (183 USPQ 288 (CCPA 1974); "Langer"):

As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented <u>must</u> be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter <u>unless</u> there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

Langer at 297, emphasis in original. As set forth in the MPEP, "Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered 'false' by a person of ordinary skill in the art" (MPEP, Eighth Edition at 2100-40, emphasis added). Thus, absent such evidence from the Examiner concerning the role of the presently claimed sequence encodes a protein kinase, the present claims clearly meet the requirements of 35 U.S.C. § 101.

The Action also disregards Applicant's asserted utility of the presently claimed polynucleotides on DNA chips (Action at page 3, Section 4.(ii)). Further, the Action seems to be requiring Applicants to identify the biological role of the nucleic acid or function of the protein encoded by the presently claimed polynucleotides before the present sequences can be used in gene chip applications that meet

the requirements of § 101. Applicants respectfully point out that knowledge of the exact function or role of the presently claimed sequence is not required to track expression patterns using a DNA chip. Given the widespread utility of such "gene chip" methods using public domain gene sequence information, there can be little doubt that the use of the presently described novel sequences would have great utility in such DNA chip applications. Particularly as Applicants have identified the protein encoded as a semaphorin, identified the specific tissues in which this gene is expressed (page 4, lines 10-15) and identified a specific polymorphism in SEQ ID NO:1 (page 17, lines 8-18). The claimed sequence provides a specific marker of the human genome (see evidence below), and that such specific markers are targets for discovering drugs that are associated with human disease. Thus, those skilled in the art would instantly recognize that the present nucleotide sequence would be an ideal, novel candidate for assessing gene expression using, for example, DNA chips, as the specification details. Such "DNA chips" clearly have utility, as evidenced by hundreds of issued U.S. Patents, as exemplified by U.S. Patent Nos. 5,445,934, 5,556,752, 5,744,305, as well as more recently issued U.S. Patent Nos. 5,837,832, 6,156,501 and 6,261,776. Accordingly, the present sequence has a specific utility in such DNA chip applications. Clearly, compositions that enhance the utility of such DNA chips, such as the presently claimed nucleotide sequence, must also be useful.

Additionally, since only a small percentage of the genome (2-4%) actually encodes exons, which in-turn encode amino acid sequences. Thus, not all human genomic DNA sequences are useful in such gene chip applications. Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101. It has been clearly established that a statement of utility in a specification must be accepted absent reasons why one skilled in the art would have reason to doubt the objective truth of such statement. *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA, 1974); *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA, 1971).

Evidence of the "real world" <u>substantial</u> utility of the present invention is further provided by the fact that there is an entire industry established based on the use of gene sequences or fragments thereof in a gene chip format. Perhaps the most notable gene chip company is Affymetrix. However, there are many companies which have, at one time or another, concentrated on the use of gene sequences or fragments, in gene chip and non-gene chip formats, for example: Gene Logic, ABI-Perkin-Elmer, HySeq and Incyte. In addition, one such company, Rosetta Inpharmatics, was viewed to have such "real world" value that it was acquired by large pharmaceutical company, Merck & Co., for substantial

sums of money (net equity value of the transaction was \$620 million). The "real world" substantial industrial utility of gene sequences or fragments would, therefore, appear to be widespread and well established. Clearly, persons of skill in the art, as well as venture capitalists and investors, readily recognize the utility, both scientific and commercial, of genomic data in general, and specifically human genomic data. Billions of dollars have been invested in the human genome project, resulting in useful genomic data (see, e.g., Venter et al., 2001, Science 291:1304). The results have been a stunning success as the utility of human genomic data has been widely recognized as a great gift to humanity (see, e.g., Jasny and Kennedy, 2001, Science 291:1153). Clearly, the usefulness of human genomic data, such as the presently claimed nucleic acid molecules, is substantial and credible (worthy of billions of dollars and the creation of numerous companies focused on such information) and well-established (the utility of human genomic information has been clearly understood for many years). The use of the claimed polypeptide in an array for screening purposes Applicants respectfully point out that nucleic acid sequences have the greatest specific utility in gene chip applications once the role of the sequence has been identified, as have tissues of interest, as in the present case. Once the role of the particular nucleic acid is known, the level of gene expression has and even greater significance. By identifying the physiological activity role of the claimed sequence, the claimed sequence has a far greater utility in gene chip applications that just any random piece of DNA.

As a still further example of utility is the use of the present sequences in such diagnostic assays (at least at page 9, line 7; page 18 line 11; page 25, line 32) as those associated with identification of paternity and forensic analysis, among others. The sequences of the present invention have particular utility as the application as filed identified a polymorphism in SEQ ID NO:1 (page 17, lines 8-18). This is also not a case of a potential utility. Appellants respectfully submit that even in the worst case scenario, the described polymorphisms are each useful to distinguish 50% of the population (in other words, the marker being present in half of the population) and that the ability of a polymorphic marker to distinguish at least 50% of the population is an inherent feature of any polymorphic marker, and this feature is well understood by those of skill in the art. Appellants note that as a matter of law, it is well settled that a patent need not disclose what is well known in the art. In re Wands, 8 USPQ 2d 1400 (Fed. Cir. 1988). Appellants support for Appellants' assertion of utility is provided by the fact that the skilled artisan would readily recognize and easily believe that the presently described polymorphic markers could be useful in forensic analysis. The fact that forensic biologists use polymorphic markers

such as those described by Appellants <u>every day</u> provides more that ample support for the assertion that forensic biologists would also be able to use the specific polymorphic markers described by Appellants in the same fashion. Therefore, again it is clear that the sequences of the present invention have utility.

Applicants respectfully submit that <u>specific</u> utility, which is the proper standard for utility under 35 U.S.C. § 101, is distinct from the requirement for a <u>unique</u> utility, which is clearly an <u>improper</u> standard. As clearly stated by the Federal Circuit in *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1101 (Fed. Cir. 1991; "*Carl Zeiss*"):

An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding a lack of utility." *Envirotech Corp. v. Al George, Inc.*, 221 USPQ 473, 480 (Fed. Cir. 1984)

Therefore, just because other nucleic acid sequences find utility in gene chip applications does not mean that the use of Applicants' sequence in gene chip applications is not a specific utility. Furthermore, the requirement for a unique utility is clearly not the standard adopted by the Patent and Trademark Office. If every invention were required to have a unique utility, the Patent and Trademark Office would no longer be issuing patents on batteries, automobile tires, golf balls, golf clubs, and treatments for a variety of human diseases, such as cancer and bacterial or viral infections, just to name a few particular examples, because examples of each of these have already been described and patented. All batteries have the exact same utility - specifically, to provide power. All automobile tires have the exact same utility - specifically, for use on automobiles. All golf balls and golf clubs have the exact same utility specifically, use in the game of golf. All cancer treatments have the exact same utility - specifically, to treat cancer. All anti-infectious agents have the exact same broader utility - specifically, to treat infections. However, only the briefest perusal of virtually any issue of the Official Gazette provides numerous examples of patents being granted on each of the above compositions every week. Furthermore, if a composition needed to be unique to be patented, the entire class and subclass system would be an effort in futility, as the class and subclass system serves solely to group such common inventions, which would not be required if each invention needed to have a unique utility. Thus, the present sequence clearly meets the requirements of 35 U.S.C. § 101.

The Action further discounts the utility of the claimed sequence for exon mapping as there is "no knowledge of what the function of the actual sequence, regardless of the basis of homology, then there is no asserted utility" (Final Action Page 4, line 4-6). Applicants respectfully submit that the function of the sequence as a semaphorin and several utilities were asserted in the application as filed (addressed above).

Although Applicants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (Raytheon v. Roper, 220 USPQ 592 (Fed. Cir. 1983); In re Gottlieb, 140 USPQ 665 (CCPA 1964); In re Malachowski, 189 USPQ 432 (CCPA 1976); Hoffman v. Klaus, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)), as a further example of the utility of the presently claimed polynucleotides, as described in the specification at least at page 12 lines 4-10, the present nucleotide sequence has a specific utility in determining the genomic structure of the corresponding human chromosome, for example mapping the protein encoding regions. As evidence supporting Applicants assertions of the specific utility of the sequences of the present invention in localizing the specific region of the human chromosome and identification of functionally active intron/exon splice junctions is the information provided as Exhibit BB. This is the result of overlaying the sequence of SEQ ID NO:1 of the present invention and the identified human genomic sequence. By doing this, one is able to identify the portions of the genome that encode the present invention. As these regions of the genome are non-contiguous, this is indicative of individual exons. The results of such an analysis indicate that the sequence of the present invention is the result of a 16 exon gene contained within the BAC clone AC006208.3. Clearly as the gene of the present invention is encoded by 16 non-contiguous exons on chromosome 3, one would not have been able to deduce the sequence that encodes the molecules of the present invention without knowing the sequence. Clearly, the present polynucleotide provides exquisite specificity in localizing the specific region of human chromosome 3 that contains the gene encoding the given polynucleotide, a utility not shared by virtually any other nucleic acid sequences. In fact, it is this specificity that makes this particular sequence so useful.

Early gene mapping techniques relied on methods such as Giemsa staining to identify regions of chromosomes. However, such techniques produced genetic maps with a resolution of only 5 to 10 megabases, far too low to be of much help in identifying specific genes involved in disease. The skilled artisan readily appreciates the significant benefit afforded by markers that map a specific locus of the

human genome, such as the present nucleic acid sequence. Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Equally significant is that the claimed polynucleotide sequences define how the encoded exons are actually spliced together to produce an active transcript (*i.e.*, the described sequences are useful for functionally defining exon splice-junctions). The presently claimed sequence clearly identified the intron/exon boundaries, as described above. The specification details that "sequences derived from regions adjacent to the intron/exon boundaries of the human gene can be used to design primers for use in amplification assays to detect mutations within the exons, introns, splice sites (*e.g.*, splice acceptor and/or donor sites), *etc.*, that can be used in diagnostics and pharmacogenomics" (specification at page 8, lines 14-20). Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Applicants again draw attention to the distinction between the requirements of a <u>specific</u> utility with a <u>unique</u> utility. The fact that a <u>small number</u> of other nucleotide sequences could be used to map the protein coding regions in this <u>specific</u> region of chromosome 3 does not mean that the use of Applicants' sequence to map the protein coding regions of chromosome 3 is not a <u>specific</u> utility (*Carl Zeiss Stiftung v. Renishaw PLC*, *supra*).

Finally, while Applicants are well aware of the new Utility Guidelines set forth by the USPTO, it has been long established that the current rules regarding the examination of patent applications is and always has been the patent laws as set forth in 35 U.S.C. and the patent rules as set forth in 37 C.F.R., not the Manual of Patent Examination Procedure or particular guidelines for patent examination set forth by the USPTO. Furthermore, it is the job of the judiciary, not the USPTO, to interpret these laws and rules. Applicants point out that guidelines that are not consistent with the patent laws, or the interpretation of these laws by the judicial branch, are not the final word in determining whether or not claims comply with any particular section of the patent laws. Applicants are unaware of any significant–recent changes in either 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit that is in keeping with the new Utility Guidelines set forth by the USPTO. This is underscored by numerous patents that have been issued over the years that claim nucleic acid fragments that do not comply with the new Utility Guidelines. As examples of such issued U.S. Patents, the Examiner is invited to review U.S. Patent Nos. 5,817,479, 5,654,173, and 5,552,281 (each of which claim short polynucleotides), none of which contain examples of the "real-world" utilities that

seem to be required in the Action. As issued U.S. Patents are presumed to meet <u>all</u> of the requirements for patentability, including 35 U.S.C. §§ 101 and 112, first paragraph (see Section III, below), Applicants submit that the presently claimed polynucleotides must also meet the requirements of 35 U.S.C. § 101. While Applicants understand that each patent application is examined on the basis of its individual merits, Applicants are unaware of any changes to 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit, since the issuance of these patents that render the subject matter claimed in these patents, which is similar to the subject matter in question in the present application, as suddenly non-statutory or failing to meet the requirements of 35 U.S.C. § 101. The requirement of Applicants to meet a <u>different</u> standard of utility in the present case would be arbitrary and capricious, and cannot stand.

In summary, the present situation is similar to Example 10 of the Revised Interim Utility Guidelines Training Materials (pages 53-55), which establishes that a rejection under 35 U.S.C. § 101 as allegedly lacking a patentable utility and under 35 U.S.C. § 112, first paragraph as allegedly unusable by the skilled artisan due to the alleged lack of patentable utility, is not proper when the full length sequence of the invention encodes a protein that has a well known function. Furthermore this response has described a series of additional substantial, specific, credible and well-established utilities for the present invention in addition to those described in Applicants' many previous responses. Therefore, Applicants submit that as the presently claimed sequence molecules have been shown to have a substantial, specific, credible and well-established utility, the rejection of the claims under 35 U.S.C. § 101 has been overcome. Thus, Applicants respectfully request that the rejection be withdrawn.

## V. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

Claims 1-4, 11-12 are also rejected under 35 U.S.C. § 112 first paragraph. Specifically, since the claimed invention is not supported by either specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants submit that all claims have been shown to have "a specific, substantial, and credible utility", as detailed above. Applicants therefore request that the rejection of all claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

## VI. Rejection of Claims Under 35 U.S.C. § 101 & 35 U.S.C. § 112

Claims 11-12 are rejected under the above 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, allegedly based on the same reasoning as above. As claims 11 and 12 are dependent upon Claim 4 and Claim 4 has now been shown to have a patentable utility under 35 U.S.C. Sections 101 and 112, this rejection has been avoided and Applicants, therefore, request withdrawal of the rejection.

#### VII. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Chism have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

<u>September 22, 2003</u>

Date

Lance K Ishimoto

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**Customer # 24231** 



#### Exhibit AA

Page 1 of 5
RECEIVED
SEP 30 700

FASTA searches a protein or DNA sequence data bank version 3.3t05 March 30, 2000
Please cite:
W.R. Pearson & D.J. Lipman PNAS (1988) 85:2444-2448

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•		730	740	750	760	770	780
	LEX151	GACAAGGTGTAC	TTCTTCTTCTCG	GAGACGGTCC	CCTCGCCCGA	TGGTGGCTC	GAACCAT
	11005		:::::::::::::::::::::::::::::::::::::::				
	g1 89/	GACAAGGTGTAC 730	740	GAGACGGTCC 750	760	TGGTGGCTC0	JAACCAT 780
_	LEX151	790 GTCACTGTCAGC	800 CGCGTGGGCCGC	810 GTCTGCGTGA	820 ATGATGCTGG	830 GGGCCAGCG0	840 -GTGCTG
		:::::::::::	::::::::::	: : : : : : : : :	:::::::::		::::::
	gi 897	GTCACTGTCAGC					
		790	800	810	820	830	840
	T EV151	850 GTGAACAAATGG.	860	870	880	890	900
		::::::::::					
		GTGAACAAATGG					
		850	860	870	880	890	900
		910	920	930	940	950	960
		GGTGCCGAGACC					
	ai 897	:::::::: GGTGCCGAGACC(	: : : : : : : : : : : : : : : : : : :	:::::::: :ጥ໓ሮአሮሮአጥሮ	TCTTCCTCC	::::::::::::::::::::::::::::::::::::::	:::::
	3-100/	910	920	930	940	950 950	960
		970	980	990	1000	1010	1020
				,-	- <del>-</del>		

LEX151	AAGAGCCTCGA	AGGTGTACGCGC	TGTTCAGCAC	CGTCAGTGCC	STGTTCCAGG	GCTTCGCC
		:::::::::::::::::::::::::::::::::::::::				
gi 897	AAGAGCCTCGA					
	970	980	990	1000	1010	1020
	1020	1040	1050	1000	1070	1000
T DV1 E 1	1030	1040	1050	1060	1070	1080
PEYIOI	. GTCTGTGTGT	CCACATGGCAG				
ai 1897	GTCTGTGTGT					
gi   o y /	1030	1040	1050	1060	1070	1080
	. 1030	1040	1050	1000	1070	1000
	1090	1100	1110	1120	1130	1140
LEX151	GATGGGCCTCA					
• • • • • • • • • • • • • • • • • • • •						
gi 897	GATGGGCCTCA	GCACCAGTGGG	GGCCCTATGG	GGCAAGGTGC	CCTTCCCTC	GCCCTGGC
·	1090	1100	1110	1120	1130	1140
	1150	1160	1170	1180	1190	1200
LEX151	GTGTGCCCCAG					
		:::::::::::::::::::::::::::::::::::::::				
gi 897	GTGTGCCCCAG					
	1150	1160	1170	1180	1190	1200
	1010	1000	1020	1040	1050	1000
T DV151	1210	1220	1230	1240	1250	1260
PEVIOI	CCAGATGAGGT	GCTGCAGTTTG(				
ai 1897	CCAGATGAGGT					
griosi	1210	1220	1230	1240	1250	1260
	1210	. 1220	1230	1240	1230	1200
	1270	1280	1290	1300	1310	1320
LEX151	CGACATGGCCG					
		:::::::::::::::::::::::::::::::::::::::				
gi 897	CGACATGGCCG	CCCTGTCCTTGT	CAAGACCCAC	CTGGCCCAGC	AGCTACACC <i>A</i>	GATCGTG
	1270	1280	1290	1300	1310	1320
	1330	1340	1350	1360	1370	1380
LEX151	GTGGACCGCGT	GGAGGCAGAGGA	TGGGACCTAC	GATGTCATTT	TCCTGGGGAC	TGACTCA
		:::::::::::::::::::::::::::::::::::::::			<b></b>	
gi 897	GTGGACCGCGT				TCCTGGGGAC	TGACTCA
	1330	1340	1350	1360	1370	1380
	1390	1400	1410	1420	1420	1.4.40
-T-FY-1-5-1-	-GGGTCTGTGCT	1400	1410	1420	1430	1440
DD21171		::::::::::::				
gi 897	GGGTCTGTGCT					
3-102.	1390	1400	1410	1420	1430	1440
		2200	1110	2130	1430	1440
	1450	1460	1470	1480	1490	1500
LEX151	GTTCTGGAGGA	GCTCCAGGTGTT				
		: : : : : : : : : : :				
gi 897	GTTCTGGAGGA	GCTCCAGGTGTT	TAAGGTGCCA	ACACCTATCA	CCGAAATGGA	GATCTCT
	1450	1460	1470	1480	1490	1500
	1510	1520	1530	1540	1550	1560
LEX151	GTCAAAAGGCAA					
	:::::::::::::::::::::::::::::::::::::::	:::::::::::::::::::::::::::::::::::::::	:::::::::::	: : : : : : : : : :	:::::::::::::::::::::::::::::::::::::::	::::::
g1 897	GTCAAAAGGCAA					
	1510	1520	1530	1540	155 <sub>.</sub> 0	1560
	1570	1500	1500	1.000	1610	1.000
	15/0	1580	1590	1600	1610	1620

LEX151 CAATGTGAG	GACTTACGGCACTG	CCTGTGCAGAG	GTGCTGCCTG(	GCCCGGGACC(	CATACTGT
	::::::::::::::::::::::::::::::::::::::				
gi 897 CAATGTGAG 157		1590	1600	1610	CATACTGT 1620
163 LEX151 GCCTGGGAT			1660	1670 GCAAGCGCC	1680
::::::::	:::::::::::::::::::::::::::::::::::::::	:::::::::::::::::::::::::::::::::::::::	:::::::::	:::::::::	
gi 897 GCCTGGGAT 163		CCCACTACCGC 1650			
	0 1040	1650	1660	1670	1680
169		1710		1730.	1740
LEX151 CGGCAGGAC	ATCCGGCACGGCAZ :::::::::::::::				
gi 897 CGGCAGGAC	ATCCGGCACGGCA	ACCCTGCCCTG	CAGTGCCTGG	GCCAGAGCCA	
169	0 1700	1710	1720	1730	1740
175		1770	1780	1790	1800
LEX151 GAGGCAGTG					
gi 897 GAGGCAGTG	::::::::::::::::::::::::::::::::::::::	CCACCATGGTC	:::::::: TACGGCACGG	:::::::: ACCACAATAC	:::::: Caccmmc
175		1770	1780	1790	1800
. 101	1000	1000	4040		
1810 LEX151 CTGGAGTGC	) 1820 TTGCCCAAGTCTCC	1830	1840	1850	1860
::::::::	::::::::::::::::::	:::::::::	:::::::::	:::::::::	::::::
gi 897 CTGGAGTGC	CTGCCCAAGTCTCC	CCAGGCTGCT	GTGCGCTGGC	TCTTGCAGAG(	GCCAGGG
1810	1820	1830	1840	1850	1860
1870	1880	1890	1900	1910	1920
LEX151 GATGAGGGG		GACGGACGAG	CGAGTCTTGC	ACACGGAGCG	GGGCTG
ai 1997 CAMCACCCC	::::::::::::::	:::::::::::::::::::::::::::::::::::::::		::::::::	::::::
gi 897 GATGAGGGGC	CIGACCAGGIGAA 1880	.GACGGACGAGC	CGAGTCTTGC 1900	ACACGGAGCG( 1910	GGGGCTG 1920
,	2000	1000	1500	1910	1920
1930			1960	1970	1980
LEX151 CTGTTCCGCA	GGCTTAGCCGTTT	CGATGCGGGCA	ACCTACACCT	CACCACTCTC	GAGCAT
gi 897 CTGTTCCGCA	GGCTTAGCCGTTT	::::::::::::::::::::::::::::::::::::::	::::::::::::::::::::::::::::::::::::::	::::::::::::::::::::::::::::::::::::::	::::::
1930		1950	1960	1970	1980
4.000					
1990 LEX151-GGCTTCTCCC		2010	2020	2030	2040
:::::::::	:::::::::::::::::::::::::::::::::::::::	:::::::::::::::::::::::::::::::::::::::	:::::::::		
gi   897 GGCTTCTCCC	AGACTGTGGTCCG	CCTGGCTCTGG	TGGTGATTGT	GGCCTCACAG	CTGGAC
1990	2000	2010	2020	2030	2040
2050	2060	2070	2080	2090	2100
LEX151 AACCTGTTCC	CTCCGGAGCCAAA	GCCAGAGGAGC	CCCCAGCCCG	GGGAGGCCTG	GCTTCC
:::::::::	:::::::::::::::::::::::::::::::::::::::		::::::::::	:::::::::	:::::
gi 897 AACCTGTTCC	CTCCGGAGCCAAA( 2060	GCCAGAGGAGC 2070			
2030	2000	2070	2080	2090	2100
2110	2120	2130	2140	2150	2160
LEX151 ACCCCACCCA	AGGCCTGGTACAAG	GACATCCTGC	AGCTCATTGG	CTTCGCCAAC	CTGCCC
gi 897 ACCCCACCCA	::::::::::::::::::::::::::::::::::::::	::::::::::::::::::::::::::::::::::::::	:::::::: ACCTC A TTCC	::::::::::::::::::::::::::::::::::::::	::::::
2110	2120	2130	2140	2150	2160
0150	04.00	0100	0000	•	
2170	2180	2190	2200	2210	2220

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LEX151 CGGGTGGATGAGTACTGTGAGCGCGTGTGGTGCAGGGGCACCACGGAATGCTCAGGCTGC
       gi|897 CGGGTGGATGAGTACTGTGAGCGCGTGTGGTGCAGGGGCACCACGGAATGCTCAGGCTGC
                                                        2220
                                      2200
                                               2210
            2170
                     2180
                              2190
                              2250
                                      2260
                                               2270
                     2240
            2230
LEX151 TTCCGGAGCCGGAGCCGGGCAAGCAGGCCAGGGCAAGAGCTGGGCAGGGCTGGAGCTA
       gi|897 TTCCGGAGCCGGAGCCGGGCCAAGCAGGCCAGGGCAAGAGCTGGGCAGGGCTGGAGCTA
                              2250
                                      2260
                     2240
            2230
                                                        2340
            2290
                     2300
                              2310
                                      2320
                                               2330
LEX151 GGCAAGAAGATGAAGAGCCGGGTGCATGCCGAGCACAATCGGACGCCCCGGGAGGTGGAG
      gi|897 GGCAAGAAGATGAAGAGCCGGGTGCATGCCGAGCACAATCGGACGCCCCGGGAGGTGGAG
                                               2330
                                      2320
LEX151 GCCACGTAG
       :::::::
gi | 897 GCCACGTAGAAGGGGGCCAGAGGAGGGGTGGTCAGGATGGGCTGGGGGGCCCACTAGCAGC
                                      2380
                                               2390
                                                        2400
                             2370
            2350
                     2360
>>gi|8978201|dbj|AB029496.1| Homo sapiens mRNA for semap
rev-comp initn: 136 init1: 78 opt: 78
 85.714% identity in 21 nt overlap (875-855:476-496)
         900
                  890
                           880
                                    870
                                             860
                                                     850
LEX15- GCACCACCAGGGCCGGGCACCGAGCAGACCAGCCTTGAGGAAAGTGCTCCATTTG
                                 :::::::: :: :::::::::
gi|897 GCCACCGTGGGGAGCATGTGCTCCACCTGGAGCCTGGCAGTGTGGAAAGTGGCCGGGGGC
                          470
                                   480
        450
                 460
                  830
                           820
                                    810
                                            800
                                                     790
         840
LEX15- TTCACCAGCACCCGCTGGCCCCCAGCATCATTCACGCAGACGCGGCCCACGCGGCTGACA
gi | 897 GGTGCCCTCACGAGCCCAGCCGTCCCTTTGCCAGCACCTTCATAGACGGGGAGCTGTACA
                                            550
                                                     560
                 520
                          530
                                   540
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2349 residues in 1 query sequences

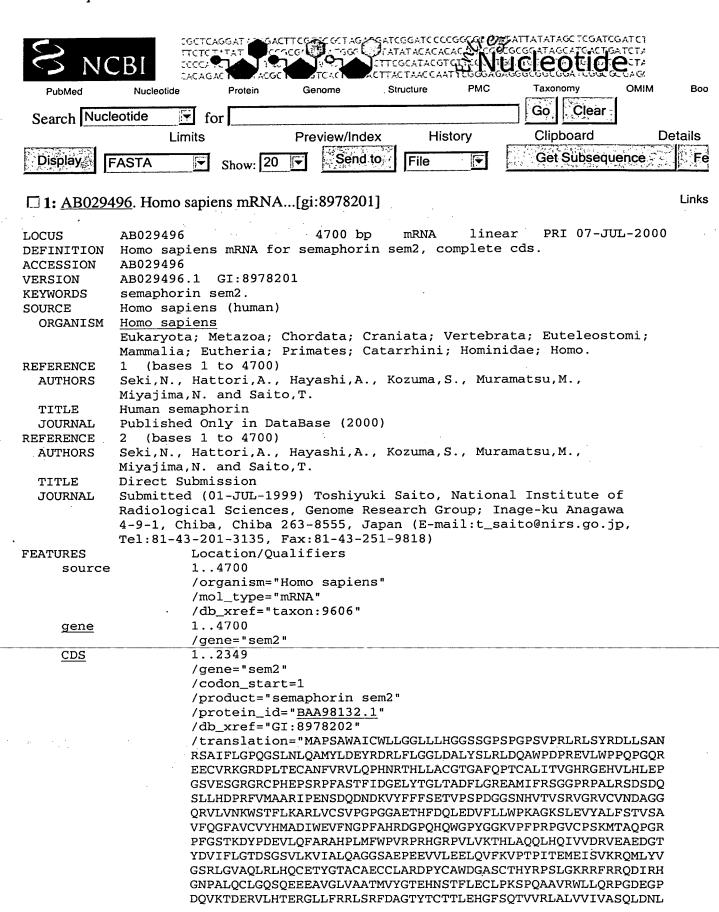
4700 residues in 1 library sequences

Scomplib [version 3.3t05 March 30, 2000]

start: Fri Sep 19 13:51:42 2003 done: Fri Sep 19 13:51:42 2003

Scan time: 0.100 Display time: 0.150

Function used was FASTA



# FPPEPKPEEPPARGGLASTPPKAWYKDILQLIGFANLPRVDEYCERVWCRGTTECSGC FRSRSRGKQARGKSWAGLELGKKMKSRVHAEHNRTPREVEAT"

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11

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<u>Disclaimer | Write to the Help Desk</u> <u>NCBI | NLM | NIH</u>

Sep 4 2003 10:24:36

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FASTA searches a protein or DNA sequence data bank
 version 3.3t05 March 30, 2000
Please cite:
W.R. Pearson & D.J. Lipman PNAS (1988) 85:2444-2448
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 Scan time: 0.117
The best scores are:
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                                               (4700 nt)
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                            280
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                                            300
    250
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gi|897
                                                    30
                                            2.0
            320
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LEX151 CTGCTAGGGGGCCTCCTGCTCCATGGGGGTAGCTCTGGCCCCAGCCCCGGCCCCAGTGTG
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                    50
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           220
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280
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                                   310
                                           320
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            620
                    630
                            640
                                    650
                                            660
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LEX151	GATCCT	TTGACAGAGT	GCGCCAACT	rcgtgcgggt(	GCTACAGCCT	CACAACCGGA	CCCAC
: 1007					::::::::::::::::::::::::::::::::::::::		
g1 897	GATCUT	"I"IGACAGAGI 340	350	360	GCTACAGCCT( 370	380	390
-	70	680	690	700	710 CTGTGCCCTC	720	CCCAC
PEXIDI	•				: : : : : : : : : : : : : : : : : : :		
gi 897					CTGTGCCCTCA		
		400	410	420	430	440	450
7	30	740	750	760	770	780	
					rgtggaaagte		GGTGC
					: : : : : : : : : : :		
gi 897	CGTGGG	GAGCATGTGC 460	TCCACCTGGA 470	AGCCTGGCAGT	TGTGGAAAGTC 490	GCCGGGGGC 500	GGTGC 510
		400	4,0	400	400	300	310
	90	800	810	820	830	840	
LEX151					CATAGACGGGG		
gi 897					CATAGACGGGG		
• ,		520	530	540	550	560	570
01	50	860	870	880	890	900	
					CTTCCGAAGTG		GGCCA
gi 897	CTCACT	GCTGACTTCC 580	TGGGGCGAGA 590	GGCCATGATC 600	CTTCCGAAGTG 610		GGCCA 630
		580	590	600	910	620	630
	10	920	930	940	950	960	
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gi 897					GACCCCCGGT		
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					GTGTACTTCT		AGACG
gi 897	CGGATC				GTGTACTTCT		
		700.	710	720	730	740	750
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gi 897					GTCAGCCGCG		
3-1		760	770	780	790	800	810
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gi 897	GTGAAT				AAATGGAGCA		
		820	830	840	850	860	870
115	0	1160	1170	1180	1190	1200	
LEX151					GAGACCCACT'		
ai 1897					::::::: GAGACCCACT'		
3-1001	-1000100	880	890	900	910	920	930
40-	^	1000	1000	1045	4055		
121	U	1220	1230	1240	1250	1260	

LEX151	L GATGT	GTTCCTGC	TGTGGCCCAA	GCCGGGAAG.	AGCCTCGAGG	TGTACGCGCT	GTTCAGC
			:::::::::				
gi 897	GATGT		TGTGGCCCAAC				
		940	950	960	970	980	990
	270		1290			1320	a. mamaa
LEX151			TGTTCCAGGGC				
~:1007			TGTTCCAGGGC				
g1   69 /	ACCGT	1000	1010	1020	1030	ACATGGCAGA 1040	1050
		1000	1010	1020	1030	1040	1030
13	30	1340	1350	1360	1370	1380	
			GGCCCTTTGCC				CCCCTAT
			::::::::::	4.	•		
gi 897			GGCCCTTTGCC				
• ,		1060	1070	1080	1090	1100	1110
13	90	1400	1410	1420	1430	1440	
LEX151	GGGGG	CAAGGTGC	CCTTCCCTCGC	CCTGGCGTG	rgccccagca/	AGATGACCGC.	ACAGCCA
			::::::::::::				
gi 897	GGGGG	CAAGGTGC	CCTTCCCTCGC	CCTGGCGTGT	rgcccagca:	AGATGACCGC.	ACAGCCA
		1120	1130	1140	1150	1160	1170
	50		1470				
LEX151			GCAGCACCAAG				
			: : : : : : : : : : :				
g1   897	GGACG		GCAGCACCAAG				
		1180	1190	1200	1210	1220	1230
. 15	10	1520	1530	1540	1550	1560	
			TOTGGCCTGTG			1560	מא א כי א כי כי
TINTI			::::::::::				
ai 1897			CTGGCCTGTG				
9-105.	0000	1240		1260		1280	1290
		1210	1230	1200	1270	1200	1270
15	70	1580	1590	1600	1610	1620	
LEX151	CACCTO	GCCCAGC	AGCTACACCAG	ATCGTGGTGG	ACCGCGTGGA	GGCAGAGGA	rgggacc
	:::::				:::::::::	:::::::::	::::::
gi 897	CACCTO	GCCCAGC	AGCTACACCAG	ATCGTGGTGG	ACCGCGTGGA	GGCAGAGGA	rgggacc
		1300.	1310	1320	1330	1340	1350
163		1640	1650	1660	1670	1680	
LEX151			CCTGGGGACT				
g1 89/	TACGAT		CCTGGGGACT				
		1360	1370	1380	1390	1400	1410
169	20	1700	1710	1720	1730	1740	
_	-		TGAACCTGAG(			1740	1
			:::::::::::				
gi 897			TGAACCTGAG				
9						00110010111	1110010
					1450	1460	1470
		1420	1430	1440	1450	1460	1470
175					1450 1790	1460 1800	1470
	50	1420 1760	1430	1440 1780	1790	1800	
	0 CCAACA	1420 1760 CCTATCAC	1430 1770	1440 1780 ATCTCTGTCA	1790 AAAGGCAAAT	1800 GCTATACGTG	GGCTCT
LEX151	0 CCAACA	1420 1760 CCTATCAC	1430 1770 CGAAATGGAGA	1440 1780 ATCTCTGTCA	1790 AAAGGCAAAT ::::::::	1800 GCTATACGTG	GGCTCT
LEX151	0 CCAACA :::::: CCAACA	1420 1760 CCTATCAC	1430 1770 CGAAATGGAGA	1440 1780 ATCTCTGTCA	1790 AAAGGCAAAT ::::::::	1800 GCTATACGTG	GGCTCT
LEX151	0 CCAACA :::::: CCAACA	1420 1760 CCTATCAC ::::::: CCTATCAC	1430 1770 CGAAATGGAGA :::::::: CGAAATGGAGA	1440 1780 ATCTCTGTCA ::::::: ATCTCTGTCA	1790 AAAGGCAAAT :::::::: AAAGGCAAAT	1800 GCTATACGTG :::::::: GCTATACGTG	GGCTCT ::::::

	CGGCTGGGTGTGGCC					
gi 897 (	::::::::::::::::::::::::::::::::::::::	CAGCTGCGG	:::::::: TTGCACCAAT	:::::::: GTGAGACTTA	CGGCACTGC	TTGTGCA
	1540	1550	1560	1570	1580	1590
1870			1900	1910	1920	
	GAGTGCTGCCTGGCC					
	::::::::::::::::::::::::::::::::::::::					
			1020	1030	1040	1030
1930 LEX151 (	) 1940 CGCCCAGCCTTGGC			1970 AGGACATCCG	1980	CCTCCC
	:::::::::::::::::::::::::::::::::::::::					
	CGCCCAGCCTTGGC	AAGCGCCGGT	TCCGCCGGC1			
	1660	1670	1680	1690	1700	1710
1990				2030	2040	
	TGCAGTGCCTGGGC					
ail997 C	TGCAGTGCCTGGGC	:::::::::				::::::
91/03/	1720	1730	AAGAAGAGGC 1740	AGTGGGACT. 1750	TGTGGCAGCC. 1760	ACCATG 1770
	1,20	1730	1740	1730	1700	1//0
2050			2080		2100	
	TCTACGGCACGGAG					
: ~: 007_0	:::::::::::::::::::::::::::::::::::::::	:::::::::	:::::::::::::::::::::::::::::::::::::::	::::::::::	::::::::	:::::
g1 89/ G	TCTACGGCACGGAG					
	1780	1790	1800	1810	1820	1830
2110	2120	2130	2140	2150	2160	
LEX151 G	CTGTGCGCTGGCTC	TTGCAGAGGC	CAGGGGATGA	GGGGCCTGAC		ACGGAC
:	:::::::::::::::::::::::::::::::::::::::	::::::::	:::::::::::	:::::::::	:::::::::	:::::
g1 897 G	CTGTGCGCTGGCTC					
	1840	1850	1860	1870	1880	1890
2170	2180	2190	2200	2210	2220	
LEX151 G	AGCGAGTCTTGCAC <i>i</i>					SATGCG
:	:::::::::::::::::::::::::::::::::::::::	:::::::::::::::::::::::::::::::::::::::	:::::::::	::::::::::	:::::::::	:::::
gi 897 G	AGCGAGTCTTGCAC					SATGCG
	1900.	1910	1920	1930	1940	1950
2230	2240	2250	2260	2270	2280	
LEX151_G	GCACCTACACCTGCA	ACCACTCTGG/	GCATGGCTT	CTCCCAGACT	GTGGTCCGCC	TGGCT
: -: 1007 G	:::::::::::::::::::::::::::::::::::::::		::::::::	:::::::::	:::::::::::::::::::::::::::::::::::::::	:::::
griss/ G	GCACCTACACCTGCA 1960	CCACTCTGGA 1970				
	1900	1970	1980	1990	2000	2010
2290	2300	2310	2320	2330	2340	
LEX151 CT	rggtggtgattgtgg	CCTCACAGCT	GGACAACCT	STTCCCTCCG	GAGCCAAAGC	CAGAG
::		::::::::::		::::::::	:::::::::	:::::
g1   89 / C1	GGTGGTGATTGTGG 2020					
	2020	2030	2040	2050	2060	2070
2350	2360	2370	2380	2390	2400	
LEX151 GA	GCCCCAGCCCGGG				rggtacaagg	ACATC
::	:::::::::::::::::::::::::::::::::::::::	:::::::::	::::::::::	:::::::::		:::::
g1 897 GA	GCCCCAGCCCGGG					
	2080	2090	2100	2110	2120	2130
2410	2420	2430	2440	2450	2460	

```
LEX151 CTGCAGCTCATTGGCTTCGCCAACCTGCCCGGGTGGATGAGTACTGTGAGCGCGTGTGG
      gi | 897 CTGCAGCTCATTGGCTTCGCCAACCTGCCCCGGGTGGATGAGTACTGTGAGCGCGTGTGG
                  2150
                          2160
                                  2170
           2480
                   2490
                           2500
   2470
                                   2510
                                          2520
LEX151 TGCAGGGCCACCACGGATGCTCAGGCTGCTTCCGGAGCCGGAGCCGGGCCAAGCAGGCC
      gi | 897 TGCAGGGGCACCACGGAATGCTCAGGCTGCTTCCGGAGCCGGAGCCGGGGCAAGCAGGCC
                  2210
                          2220
                                  2230
   2530
           2540
                   2550
                           2560
                                  2570
                                          2580
LEX151 AGGGGCAAGAGCTGGGCAGGGCTGGAGCTAGGCAAGAAGATGAAGAGCCGGGTGCATGCC
      gi | 897 AGGGGCAAGAGCTGGGCAGGCTGGAGCTAGGCAAGAAGATGAAGAGCCGGGTGCATGCC
          2260
                  2270
                          2280
                                 2290
           2600
                   2610
                          2620
LEX151 GAGCACAATCGGACGCCCCGGGAGGTGGAGGCCACGTAG
      gi | 897 GAGCACAATCGGACGCCCCGGGAGGTGGAGGCCACGTAGAAGGGGGCCAGAGGAGGGGTGG
          2320
                  2330
                          2340
                                 2350
2380
                  2390
                          2400
                                 2410
>>gi|8978201|dbj|AB029496.1| Homo sapiens mRNA for semap (4700 nt)
rev-comp initn: 83 init1: 83 opt: 95
67.105% identity in 76 nt overlap (119-46:407-475)
           140
                  130
                          120
LEX15- GCGGGAAGAGGGGGGGGAGAGAAGGAGGAGGCTTGCCGTTCCACCTGCCGCTTCT
                             gi|897 ACAACCGGACCCACCTGCTAGCCTGTGGCACTGGGGCCCTTCCAGCCCACCTGTGCC--CT
              390
                      400
                                     420
                                             430
           80
                    70
                             60
                                            40
LEX15- CCTTCCACCTTGTTGGCC-CAGTGCAG-GCTTTTGTGCCACACTGGCCAGCTCCCCATTG
     gi|897 CATCACA----GTTGGCCACCGTGGGGAGCATGTGCTCCAC-CTGGAGCCTGGCAGTGTG
                  450
                          460
     30 20 10
LEX15- GGAAGACCTTCCCAGCTAGGGCACAGGCCAT
gi|897 GAAAGTGGCCGGGGGGGGTGCCCTCACGAGCCCAGCCGTCCCTTTGCCAGCACCTTCATA
   490
           500
                           520
                                   530
```

```
2628 residues in 1 query sequences
4700 residues in 1 library sequences
Scomplib [version 3.3t05 March 30, 2000]
start: Fri Sep 19 13:50:44 2003 done: Fri Sep 19 13:50:45 2003
Scan time: 0.117 Display time: 0.133
```

Function used was FASTA

#### Exhibit BB

		·			
Home	Paracel BLAS	ST Results		Help	
MEGABLAST 1.2.3	3-Paracel [2001-11-20]				
Reference:	-				
Zheng Zhang, So "A greedy algor J Comput Biol 2 Database: Homo	cott Schwartz, Lukas Wag rithm for aligning DNA s 2000; 7(1-2):203-14. _sapiens.latestgp.fa 579 sequences; 200,800,6	equences",			
Query= 1	•			et in the	
. (2629	letters)			4	
Sequences produ	ncing significant alignm	ents:		Score (bits)	E Value
AC006208.3.1.12 AC000063.1.1.34					0.0 2e-09
AC079799.7.1.17					5e-04
>AC006208.3.1.1 Lengt	.23943 h = 123943				
	oits (474), Expect = 0.0 74/474 (100%)	•			
Strand = Plus	•				
Query: 2156 ca	ggtgaagacggacgagtct	tgcacacggagcggg	gactactattccac	aggett	2215
		[			
·				aggeee	44437
Query: 2216 ag	ccgtttcgatgcgggcacctacad	cctgcaccactctgg	agcatggcttctcc	cagact	2275
Sbjct: 44456 ag	ccgtttcgatgcgggcacctacad	cctgcaccactctgg	agcatggcttctcc	cagact	44397
Query: 2276 gt	aatacaactaactctaataataa	tataaataaaa	taanan aatatta	aataaa	2225
	ggtccgcctggctctggtggtgat 				
55)cc. 44590 gc	ggtccgcctggctctggtggtgat	tgtggeeteaeage	tggacaacctgttc	cctccg	4433/
Query: 2336 gag	gccaaagccagaggagcccccagc	ccggggaggcctgg	cttccaccccaccc	aaggcc	2395
Sbjct: 44336 gag				 aaggcc	44277
2222					e Seguina
111	gtacaaggacateetgeageteat 	]	1111111111111	[	
Sbjct: 44276 tgg	gtacaaggacatcctgcagctcat	tggcttcgccaacc	tgccccgggtggat	gagtac	44217

Query: 2456 tgtgagcgcgtgtggtgcaggggcaccacggaatgctcaggctgcttccggagccggagc 2515
Sbjct: 44216 tgtgagcgcgtgtggtgcaggggcaccacggaatgctcaggctgcttccggagccggagc 44157

```
Query: 2516 cggggcaagcaggccaggggcaagagctgggcagggctggagctaggcaagaagatgaag 2575
          Sbjct: 44156 cggggcaagcaggccaggggcaagagctgggcagggctggagctaggcaagaagatgaag 44097
Query: 2576 agccgggtgcatgccgagcacaatcggacgccccgggaggtggaggccacgtag 2629
          Sbjct: 44096 agccgggtgcatgccgagcacaatcggacgccccgggaggtggaggccacgtag 44043
 Score = 781 bits (394), Expect = 0.0
 Identities = 394/394 (100%)
 Strand = Plus / Minus
          atggcctgtgccctagctgggaaggtcttcccaatggggagctggccagtgtggcacaaa 61
Query: 2
          Sbjct: 53746 atggcctgtgccctagctgggaaggtcttcccaatggggagctggccagtgtggcacaaa 53687
          agcctgcactgggccaacaaggtggaaggagaagcggcaggtggacggcaaggccccagc 121
Query: 62
          Sbjct: 53686 agcctgcactgggccaacaaggtggaaggagaagcggcaggtggacggcaaggccccagc 53627
Query: 122
          ctccttctctcctccgccctcttcccgcccaggactgggtggagccactgccttataag 181
          Sbjct: 53626 ctccttctctctccccccctcttcccgcccaggactgggtggagccactgccttataag 53567
Query: 182
          tggtggcctggtggcagcagagcaaactacaaccggcggccagcgggaccagagggcggc 241
          Sbjct: 53566 tggtggcctggtggcagcagagcaaactacaaccggcggccagcgggaccagagggcggc 53507
Query: 242
          tetgeaggeaggeggeageggtgeeeteagtteeeeageatggeeeeeteggeetgggee 301
          Sbjct: 53506 tetgeaggeaggeageggtgeeeteagtteeeeageatggeeeeteggeetgggee 53447
Query: 302
          atttgctggctgctagggggcctcctgctccatgggggtagctctggccccagccccggc 361
          Sbjct: 53446 atttgctggctgctagggggcctcctgctccatgggggtagctctggccccagccccggc 53387
Query: 362
          cccagtgtgccccgcctgcggctctcctaccgag 395
          Sbjct: 53386 cccagtgtgccccgcctgcggctctcctaccgag 53353
Score = 462 \text{ bits } (233), \text{ Expect = } e-127
Identities = 233/233 (100%)
Strand = Plus / Minus
Query: 1423
          gtgccccagcaagatgaccgcacagccaggacggccttttggcagcaccaaggactaccc 1482
```

```
Sbjct: 48539 gtgccccagcaagatgaccgcacagccaggacggccttttggcagcaccaaggactaccc 48480
 Query: 1483 agatgaggtgctgcagtttgcccgagcccacccctcatgttctggcctgtgcggcctcg 1542
           Sbjct: 48479 agatgaggtgctgcagtttgcccgagcccacccctcatgttctggcctgtgcggcctcg 48420
 Query: 1543 acatggccgccctgtccttgtcaagacccacctggcccagcagctacaccagatcgtggt 1602
           Sbjct: 48419 acatggccgccctgtccttgtcaagacccacctggcccagcagctacaccagatcgtggt 48360
 Query: 1603 ggaccgcgtggaggcagaggatgggacctacgatgtcattttcctggggactg 1655
           Sbjct: 48359 ggaccgcgtggaggcagaggatgggacctacgatgtcattttcctggggactg 48307
  Score = 456 \text{ bits } (230), Expect = e-125
  Identities = 230/230 (100%)
  Strand = Plus / Minus
 Query: 1789 gcaaatgctatacgtgggctctcggctgggtgtggcccagctgcggctgcaccaatgtga 1848
           Sbjct: 46640 gcaaatgctatacgtgggctctcggctgggtgtggcccagctgcggctgcaccaatgtga 46581
 Query: 1849
           gacttacggcactgcctgtgcagagtgctgcctggcccgggacccatactgtgcctggga 1908
           Sbjct: 46580 gacttacggcactgcctgtgcagagtgctgcctggcccgggacccatactgtgcctggga 46521
Query: 1909
           tggtgcctcctgtacccactaccgcccagccttggcaagcgccggttccgccggcagga 1968
           Sbjct: 46520 tggtgcctcctgtacccactaccgccccagccttggcaagcgccggttccgccggcagga 46461
Query: 1969 catccggcacggcaaccctgccctgcagtgcctgggccagagccaggaag 2018
Sbjct: 46460 catccggcacggcaaccctgccctgcagtgcctgggccagagccaggaag 46411
 Score = 327 \text{ bits (165)}, Expect = 2e-86
 Identities = 165/165 (100%)
 Strand = Plus / Minus
Query: 394
           agacctcctgtctgccaaccgctctgccatctttctgggcccccagggctccctgaacct 453
           Sbjct: 51349 agacctectgtetgeeaaccgetetgeeatetttetgggeeeceagggeteeetgaacet 51290
```

ccaggccatgtacctagatgagtaccgagaccgcctctttctgggtggcctggacgccct 513

Sbjct: 51289 ccaggccatgtacctagatgagtaccgagaccgcctctttctgggtggcctggacgccct 51230

Query: 454

Query: 514 ctactctctgcggctggaccaggcatggccagatccccgggaggt 558

Sbjct: 51229 ctactctctgcggctggaccaggcatggccagatccccgggaggt 51185

Score = 294 bits (148), Expect = 3e-76

Identities = 148/148 (100%)

Strand = Plus / Minus

Query: 1276 cagtgccgtgttccagggcttcgccgtctgtgtgtaccacatggcagacatctgggaggt 1335

Sbjct: 48964 cagtgccgtgttccagggcttcgccgtctgtgtgtaccacatggcagacatctgggaggt 48905

Query: 1336 tttcaacgggccctttgcccaccgagatgggcctcagcaccagtgggggccctatggggg 1395

Sbjct: 48904 tttcaacgggccctttgcccaccgagatgggcctcagcaccagtgggggccctatggggg 48845

Query: 1396 caaggtgcccttccctcgccctggcgtg 1423

Sbjct: 48844 caaggtgcccttccctcgccctggcgtg 48817

Score = 292 bits (147), Expect = 1e-75

Identities = 147/147 (100%)

Strand = Plus / Minus

Query: 947 gaccccggtttgtgatggccgcccggatccctgagaactctgaccaggacaatgacaag 1006

Sbjct: 49850 gacccccggtttgtgatggccgcccggatccctgagaactctgaccaggacaatgacaag 49791

Query: 1007 gtgtacttcttcttctcggagacggtcccctcgcccgatggtggctcgaaccatgtcact 1066

Query: 1067 gtcagccgcgtgggccgcgtctgcgtg 1093

Sbjct: 49730 gtcagccgcgtgggccgcgtctgcgtg 49704

Score = 286 bits (144), Expect = 6e-74

Identities = 145/146 (99%)

Strand = Plus / Minus

Query: 2017 agaagaggcagtgggacttgtggcagccaccatggtctacggcacggagcacaatagcac 2076

Sbjct: 46108 agaagaggcagtgggacttgtggcagccaccatggtctacggcacggagcacaatagcac 46049

Query: 2077 cttcctggagtgcctgcccaagtctccccargctgctgtgcgctggctcttgcagaggcc 2136

Sbjct: 46048 cttcctggagtgcctgcccaagtctccccaggctgctgtgcgctggctcttgcagaggcc 45989

Query: 2137 aggggatgaggggcctgaccaggtga 2162

Sbjct: 45988 aggggatgaggggcctgaccaggtga 45963

Score = 240 bits (121), Expect = 3e-60

Identities = 121/121 (100%)

Strand = Plus / Minus

Query: 619 gacagagtgcgccaacttcgtgcgggtgctacagcctcacaaccggacccacctgctagc 678

Sbjct: 50745 gacagagtgcgccaacttcgtgcgggtgctacagcctcacaaccggacccacctgctagc 50686

Query: 679 ctgtggcactggggccttccagcccacctgtgccctcatcacagttggccaccgtgggga 738

Sbjct: 50685 ctgtggcactggggccttccagcccacctgtgccctcatcacagttggccaccgtgggga 50626

Query: 739 g 739

Sbjct: 50625 g 50625

Score = 236 bits (119), Expect = 5e-59

Identities = 119/119 (100%)

Strand = Plus / Minus

Query: 829 agacggggagctgtacacgggtctcactgctgacttcctgggggcgagaggccatgatctt 888

Sbjct: 50132 agacggggagctgtacacgggtctcactgctgacttcctggggcgagaggccatgatctt 50073

Query: 889 ccgaagtggaggtcctcggccagctctgcgttccgactctgaccagagtctcttgcacg 947

Sbjct: 50072 ccgaagtggaggtcctcggccagctctgcgttccgactctgaccagagtctcttgcacg 50014

Score = 230 bits (116), Expect = 3e-57

Identities = 116/116 (100%)

Strand = Plus / Minus

Query: 1093 gaatgatgctgggggccagcgggtgctggtgaacaaatggagcactttcctcaaggccag 1152

Sbjct: 49489 gaatgatgctgggggccagcgggtgctggtgaacaaatggagcactttcctcaaggccag 49430

Query: 1153 gctggtctgctcggtgcccggccctggtggtgccgagacccactttgaccagctag 1208

Sbjct: 49429 gctggtctgctcggtgcccggccctggtggtgccgagacccactttgaccagctag 49374

Score = 188 bits (95), Expect = 1e-44Identities = 95/95 (100%) Strand = Plus / Minus Query: 1715 gaagtggttctggaggagctccaggtgtttaaggt 1749 Sbjct: 48152 gaagtggttctggaggagctccaggtgtttaaggt 48118 Score = 184 bits (93), Expect = 2e-43Identities = 93/93 (100%) Strand = Plus / Minus Query: 738 Query: 798 agcccagccgtccctttgccagcaccttcatag 830 1111111111111111111111111111111111111 Sbjct: 50291 agcccagccgtccctttgccagcaccttcatag 50259 Score = 143 bits (72), Expect = 6e-31Identities = 72/72 (100%) Strand = Plus / Minus Query: 1207 agaggatgttcctgctgtggcccaaggccgggaagagcctcgaggtgtacgcgctgtt 1266 Sbjct: 49265 agaggatgtgttcctgctgtggcccaaggccgggaagagcctcgaggtgtacgcgctgtt 49206 Query: 1267 cagcaccgtcag 1278 Sbjct: 49205 cagcaccgtcag 49194 Score = 129 bits (65), Expect = 9e-27

Identities = 65/65 (100%) Strand = Plus / Minus

Query: 615 ctttg 619 11111Sbjct: 51003 ctttg 50999 Score = 87.8 bits (44), Expect = 3e-14Identities = 44/44 (100%) Strand = Plus / Minus Query: 1746 aggtgccaacacctatcaccgaaatggagatctctgtcaaaagg 1789 Sbjct: 47403 aggtgccaacacctatcaccgaaatggagatctctgtcaaaagg 47360 >AC000063.1.1.34478 Length = 34478Score = 71.9 bits (36), Expect = 2e-09Identities = 48/52 (92%) Strand = Plus / Minus Query: 1860 ctgcctgtgcagagtgctgcctggcccgggacccatactgtgcctgggatgg 1911 Sbjct: 5711 ctgcctgtgctgactgctgccttgcccgggacccttactgtgcctgggatgg 5660 >AC079799.7.1.172495 Length = 172495Score = 54.0 bits (27), Expect = 5e-04Identities = 42/47 (89%) Strand = Plus / Minus Query: 1865 tgtgcagagtgctgcctggcccgggacccatactgtgcctgggatgg 1911 

Sbjct: 151014 tgtgctgactgctgctggctcgagacccttactgtgcctgggatgg 150968

Database: Homo\_sapiens.latestgp.fa
Posted date: Jul 8, 2003 12:51 PM
Number of letters in database: 200,800,637,119
Number of sequences in database: 26,679

Lambda K H
1.37 0.711 1.31

Gapped
Lambda K H
1.37 0.711 1.31

Matrix: blastn matrix:1 -3
Gap Penalties: Existence: 0, Extension: 0

```
Number of Hits to DB: 0
length of query: 5260
length of database: 200,800,637,119
effective HSP length: 22
effective length of query: 2607
effective search space used:
T: 0
A: 0
X1: 0 ( 0.0 bits)
X2: 20 (39.7 bits)
S1: 12 (24.3 bits)
S2: 24 (48.1 bits)
```